Consultant Profile
Michael Schaefer

Experience & Background

As mechanical engineer by training, I am working in medical devices since 2001. After starting-up with the basics in manufacturing for balloon catheters and cardiac stents, I got responsible for quality engineering, process validation and deployment of six-sigma tools within development and manufacturing of drug eluting stents both in Germany and Ireland.

Global Management of Pre-Production Quality and Regulatory Affairs for dialysis disposables added extensive knowledge about communication and interaction with authorities and notified bodies to my portfolio. By combining the requirements for worldwide submissions with the toolbox of Quality Management systems, I was able to shorten timelines for registration significantly and increase compliance to international standards and regulations.

Having been a Quality Director in a high volume manufacturing environment for urology catheters and airway management products, I enjoyed finally three years of decision making, problem solving and simplifying quality work flows. Making quality operations management both a compliant and value adding activity was probably one of the things I am most proud of having accomplished.

Since January 2014, I am freelancing and consulting as expert for Quality Management Systems and Regulatory Affairs for Medical Devices.

Current and past projects in several international companies include:

- PRRC as per article 15 EU 2017/745 (MDR),
- MDR preparation Stage 1 and stage 2,
- TD assessment,
- Computersystem validation,
- IQ, OQ, PQ,
- Test method validation,
- FDA Readiness,
- Interim Quality Management Representative (Class I-III),
- Design & development, including drug device combination products (MDR article 117) and medical face masks as per EN 14683,
- Production Transfer including Clean Room Validation,
- Auditing (internal, external, supplier, mock inspections),
- Laboratory Management ISO 17025.

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Since 2015, I am auditing for TUEV Sued Product Service (Lead Auditor MDD, ISO13485 and MDSAP). In 09/2019, I was authorized as QMS Lead Auditor for (EU) 2017/745 MDR for MDT2001, 2002, 2003, 2008, 2011, MDN1101_2, 1201, 1202, 1203, 1208, 1214, MDS1005_1, 1005_2, 1005_3, 1005_7 and more.

Transferring and communicating my experience and in-depth knowledge became an important part in my career. I am giving external trainings for TUEV Sued Academy, e.g., for

- MDR,

- MDSAP,

- Design Control,

- Process Validation,

- CAPA,

- Risk Management,

- Statistical techniques

- Internal Audits,

- Technical Documentation,

- Labeling of medical devices,

- Vigilance, and

- Test Method Validation.

"Let's make the Quality Experience simple and flexible, from the moment we enter Design Control until the Product Lifecycle ends. Let's optimize the value of the time spent for Quality and always aim to ensure Safety, enable Service and encourage Simplicity in Quality Management and Regulatory Affairs."

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
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